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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,341	07/21/2000	Keiji Enpuku	017348/0361	3693

7590

01/02/2003

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/621,341

Applicant(s)

ENPUKU, KEIJI

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claim Status

The amendment and formal drawings filed on October 15, 2002 have been acknowledged and entered.

Claims 1-4, 12-15 are pending.

Withdrawn Rejection(s)

Rejection under 112, second paragraph in the previous office action is withdrawn herein.

Rejections under 102(e) by NTT (JP 63090765A) and Koch are withdrawn herein.

New grounds of Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 14, 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because the preamble recites a "method for immunoassay with a magnetic material labeled a Superconducting quantum interference device". The Device is labeled with a magnetic material? If so, then the body of the claim is inconsistent with the preamble because the body recites that the analyte is labeled a magnetic material.

Claim 1 is unclear as how the labeled analyte is involved in the detection of an antigen-antibody reaction. Since the roles of the antigen and antibody have not been defined in connection with the analyte. The analyte neither binds to any antigen or antibody.

Claim 14 is confusing in reciting "moving said labeled and magnetized magnetic material label". The "labeled" magnetic material label lacks antecedent basis. No such labeled magnetic material label has been introduced in claim 12.

Claim 15 is confusing because the analyte has not been magnetized in either claim 12 or 14. The analyte has only been labeled with a magnetic material label.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 12-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working

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examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention: - the instant invention is directed to a method for immunoassay using a magnetic material label and a SQUID device comprising labeling an analyte with a magnetic material label; subjecting the magnetic material label to a magnetic field; using a SQUID to detect a variation of strength of a magnetic field which is at a right angle to the magnetic field which magnetizes the magnetic material label.

The state of the art: - the prior art teaches that the analyte is labeled with a magnetic particle coated with a binder that binds to the analyte. Then the mixture is separated by a magnetic field. After that, a fluorescent or color label is added and detection occurs.

The predictability or lack thereof in the art: - in view of the teachings in the prior art that show or suggests that the magnetic material label must have a binder that binds to the analyte, the predictability of using the magnetic material label without a binder to the analyte is low.

The amount of direction or guidance present: - the instant specification, example 3, discloses that antigen/analyte is fixed by a first antibody/capture antibody to a support. Then a second antibody binds to selectively to the antigen. Furthermore, a third antibody labeled with a magnetic material binds to the second antibody. A magnetic field is applied to the mixture. Then, the SQUID detects the magnetic material.

The presence or absence of working examples: - there is no examples in the specification that shows the analyte alone would bind to the magnetic material label

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without a binder either attached to the magnetic material label or bound to the analyte before contacting the magnetic material label. Furthermore, the specification also do not provide working examples of how the bound and unbound magnetic material labels are separated and how the various strength of magnetic field correlates to the presence/absence or concentration of the analyte.

The quantity of experimentation necessary: - it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed.

The relative skill of those in the art: The level of skill in the art is high.

The breadth of the claims:- the claimed method is directed to using a magnetic label to label analyte and subject said mixture to a magnetic field. Then the SQUID detects the various strength of a magnetic field that is perpendicular to the magnetic field, which magnetizes the magnetic label and the analyte.

The claims of the present invention recite that the analyte is labeled with a magnetic material label. Then the magnetic material label is subjected to a magnetic field without separation of the bound and unbound. In this case, the magnetic field would attract the bound and the unbound. Then how are the bound analytes distinguished from the unbound? The SQUID detects a magnetic field, which is perpendicular to the first magnetic field. However, the specification fails to correlates such detection using the SQUID with the presence/absence/concentration of the analytes being detected in the immunoassay. Without a critical element such as a second label, i.e. a fluorescent or color particle, one of ordinary skills in the art would not able to detect the analytes using just the magnetic fields. Furthermore, while the

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specification teaches that the magnetic material label is bound to a binder, second antibody, which binds the analyte, the claims fail to recite such critical element, which is essential to the practice of the invention. Thus, these claims are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Weitschies et al. (US 6,027,946).

Weitschies teaches a process for quantitative detection of analytes in liquid and solid phases by labeling an analyte of interest with colloidal ferromagnetic substances or magnetic labels (see col. 2, lines 60-65); magnetizing the magnetic labeled analytes; measuring analytes by using a SQUID (superconducting quantum interference

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device).(see col. 3, line 60-col. 4, line 2; col. 4, lines 18-36). A static magnetic field is a magnetic field that does not change and produced by a natural or synthetic magnet.

Thus, the magnetic field of Weitchies applies to the static magnetic field of the present invention. When a magnetic field is applied, the magnet is pulling the magnetic material. Magnetic fields have parallel lines of force so the analyte that is labeled with magnetic material will move parallel to the magnetic field.

Response to Arguments

Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive.

Applicant submits that the references fails to teach that the magnetic label which is magnetized by the magnetic field is detected by the SQUID which detects a variation of the strength of a magnetic field which is at a right angle to the magnetic field which magnetizes the magnetic material label.

Weitschies teaches in figure 1 that the sample is magnetized by the magnetizing coil and above that is the SQUID which detects the magnetic field. In figure 1, the magnetizing coils pull the magnetic labels to the sides that create horizontal lines of force. The SQUID that is positioned above the sample substrate detects magnetic field which is perpendicular to the horizontal lines of force created by the magnetizing coils on the side of the sample substrate.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

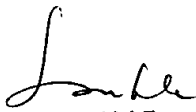
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Pensee T. Do
Patent Examiner
December 20, 2002


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12/30/02